



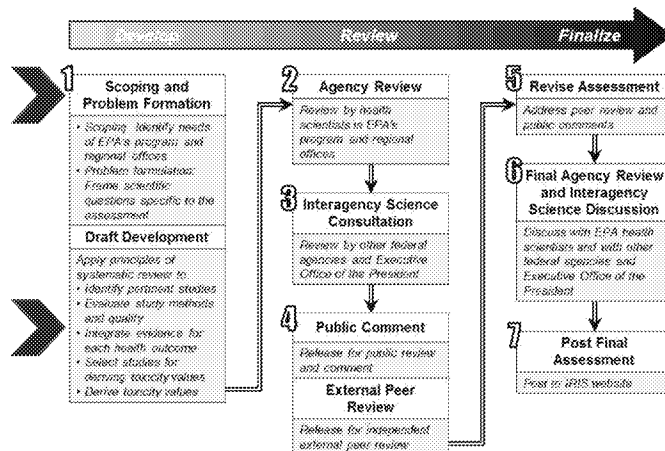
IRIS Process Refresher (Step 1)

IRIS Assessment Plan

- Agency Reviewers are given approximately 2 weeks to submit written comments.
- IAP is revised in response to Agency review, with focus on requesting office(s), and released for a 30-day public comment period.
- Public Meeting is convened to discuss IAP.

IRIS Systematic Review Protocol

- If major science issues were identified between IAP release and completion of the protocol, requesting office(s) will be engaged.
- IRIS presents an informational briefing on the protocol at an EPA-Wide IRIS Call.
- Protocol is released for a 30-day public comment period.

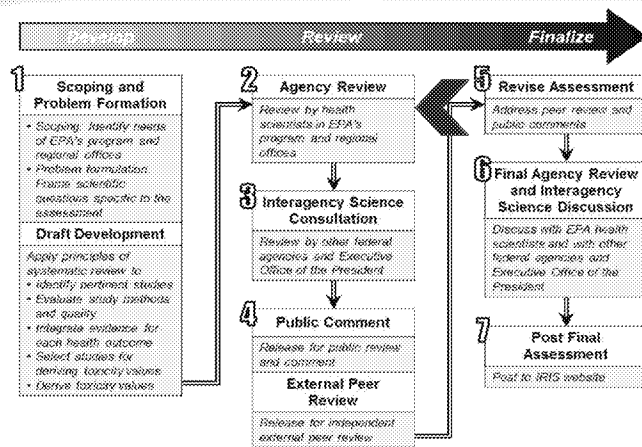


IRIS ASSESSMENT DEVELOPMENT PROCESS

The flowchart does not include the IRIS Systematic Review Protocol for 2012 IRIS assessments and the IRIS Systematic Review Protocol for 2013 IRIS assessments.



IRIS Process Refresher (Step 2 & 6)



IRIS Agency Review (Step 2)

- Agency Reviewers are given approximately 4 weeks to submit written comments.
- IRIS facilitates an Agency review meeting following the comment submission deadline. Discussion centers on major scientific issues, with focus on requesting office(s).
- Unresolved issues will be addressed with charge questions to the external peer reviewers.

Final Agency Review and Interagency Science Discussion (Step 6)

- Review steps are same as Step 2.
- Meetings with reviewers are organized to address major science issues.

IRIS ASSESSMENT DEVELOPMENT PROCESS

The IRIS process has been refined. The figure reflects current steps and documents the IRIS process, including the IRIS process and the IRIS process.



IRIS Chemical Assessment Status

Scoping and Problem Formulation (Assessment Plans)*	Protocol/Draft Development*	Agency Review	Interagency Review	Public Comment	External Peer Review	Post-EPR Revise Assessment	Final Agency/ Interagency Review
<ul style="list-style-type: none">• Methylmercury (IRIS Assess. Plan FY19 Q2)• Inorganic Mercury Salts (IRIS Assess. Plan FY19 Q4)• Vanadium and Compounds	<ul style="list-style-type: none">• Chromium VI (Protocol FY19 Q2 and public protocol webinar in April 2019)• Inorganic arsenic (Protocol FY19 Q2 and Public NAS meeting on protocol July 2019)• PCBs noncancer (Protocol FY19 Q4)• PFAS (PFNA, PFBA, PFHxS, PFHxA, PFDA)				<ul style="list-style-type: none">• ETBE & TBA (Public teleconferences to discuss draft peer review reports occurred on March 22, March 27 and June 6, 2018; awaiting quality review of draft peer review report)		
* Identified as EPA priorities in the FY19 IRIS Program Outlook https://www.epa.gov/iris/iris-program-outlook							3



IRIS Chemical Assessment Status

Hexavalent Chromium

Chemical Managers:

- Catherine Gibbons (gibbons.catherine@epa.gov)
- Alan Sasso (sasso.alan@epa.gov)

Project history:

https://cfpub.epa.gov/ncea/iris2/chemical_landing.cfm?substance_nmbr=144

Highlights of Recent Engagement and Current Information on the IRIS Database

1998	Cr(VI) Toxicological Review Posted to the IRIS Database – Known human carcinogen by inhalation; not classifiable by ingestion – Includes RfD, RfC, and IUR; no OSF
2011	External Peer Review meeting on the 2010 draft assessment (oral exposure only) – Decision to incorporate new science and revise the assessment
2013	IRIS conducts a workshop on issues regarding gastrointestinal reduction, absorption, and transit of ingested Cr(VI) in rodents and humans
2014	IRIS releases two preliminary packages for Cr(VI) for public review and discussion
Current Scope	Assessment aims to update the existing toxicity values (i.e., RfD, RfC, and IUR), and, if possible, <u>derive a new OSF</u> .

Next steps:

- Public release of IRIS Protocol in March 2019 and host a Public Science Webinar: April 24, 2019 (tentative)



IRIS Chemical Assessment Status (Continued)

Inorganic Arsenic

Chemical Managers:

- Janice Lee (lee.janices@epa.gov)
- Allen Davis (davis.allen@epa.gov)

Project history:

https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=278

Highlights of Recent Engagement and Current Information on the IRIS Database

1988	Inorganic Arsenic Toxicological Review Posted to the IRIS Database – Known human carcinogen; Includes RfD, IUR, and OSF; no RfC
2013	IRIS held a public planning/scoping meeting for development of new ToxRev-iAs and held eight science issues public webinars
2013	NRC released the interim report, <i>Critical Aspects of EPA's IRIS Assessment of iAs</i> and provided recommendations in support of EPA's plan
2014	Public science meeting on the assessment development plan, preliminary materials, and key science issues
2015	IRIS briefed the newly empaneled NRC committee on the status of iAs assessment
Current Scope	Assessment aims to derive a new noncancer toxicity value for inhalation exposure and update the existing toxicity values for oral exposure (cancer and noncancer) and the inhalation toxicity value for cancer, focusing on epidemiologic data

Next steps: Public release IRIS Protocol in Q2 FY19 and NAS meeting no earlier than Q4 FY19 (being rescheduled from March 2019 due to shutdown)



IRIS Chemical Assessment Status (Continued)

PFAS

Coordinator: Andrew Kraft (kraft.andrew@epa.gov)

Chemical	Chemical Manager
PFBA	Allen Davis (davis.allen@epa.gov) Michele Taylor (taylor.michelem@epa.gov)
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PFHxS and PFDA	Xabier Arzuaga (arzuaga.xabier@epa.gov) Ingrid Druwe (druwe.ingrid@epa.gov) Luci Lizarraga (lizarraga.lucina@epa.gov)
PFNA	Andrew Kraft (kraft.andrew@epa.gov) Pam Noyes (noyes.pamela@epa.gov) Michele Taylor (taylor.michelem@epa.gov)
Current Scope	Assessments will aim to <u>derive new cancer and noncancer toxicity values</u> , based on the available data (note: expecting only oral noncancer values)

Project history: Scoping and problem formulation were initiated as part of the EPA-wide PFAS efforts.

Next steps: Public release of the Protocol in FY19 Q3 followed by phased Agency Review (i.e., moving through the process in two groups)



IRIS Chemical Assessment Status (Continued)

Polychlorinated Biphenyls (PCBs)

Chemical Managers:

- Geniece Lehmann (lehmman.geniece@epa.gov)
- Laura Carlson (carlson.laura@epa.gov)

Project history:

https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=294

Highlights of Recent Engagement and Current Information on the IRIS Database

1993 – 1996	PCBs, including Aroclors 1016 and 1254 to IRIS – Probable human carcinogen; – Includes RfD (1993 and 1994); IUR/OSF (1996)
2015	Preliminary Assessment Materials of the IRIS assessment of PCBs is posted
Current Scope	Assessment aims to derive <u>new noncancer toxicity values for environmental PCB mixtures</u>

Notes: Preliminary materials (not in current IRIS format, but including PF decisions) discussed with public; protocol and drafts to be consistent with current NCEA systematic review practices

Next Steps: Systematic Review Protocol FY19 Q4

Methylmercury (MeHg)

Chemical Managers:

- Leonid Kopylev (kopylev.leonid@epa.gov)
- Deborah Segal (segal.deborah@epa.gov)

Project history:

https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=73

Highlights of Recent Engagement and Current Information on the IRIS Database

1995 - 2001	Methylmercury Toxicological Review Posted to IRIS – Possible human carcinogen; no OSF (1995) – Includes RfD (2001)
2017	IRIS distributes the IRIS Assessment Plan (IAP) for Methylmercury for an internal EPA review
2019	IRIS anticipates releases the IAP for public comment and discussion at an IRIS Public Science Meeting
Current Scope	Assessment aims to <u>update the existing RfD</u> , focusing on epidemiologic studies examining developmental neurotoxicity

Next Steps: Anticipated IAP release in March 2019 for public comment and public science meeting date - April 2019 (tentative)



IRIS Chemical Assessment Status (Continued)

Inorganic Mercury Salts

Chemical Manager:

- Nagalakshmi (Nagu) Keshava (Keshava.nagu@epa.gov)

Project history:

https://cfpub.epa.gov/ncea/iris2/chemical_landing.cfm?substance_nmbr=692

Highlights of Recent Engagement and Current Information on the IRIS Database

1995	Mercuric chloride (HgCl ₂) to IRIS – Possible human carcinogen; – Includes RfD (1995); no OSF or IUR.
2019	IRIS anticipates releasing the IRIS Assessment Plan for public comment
Current Scoping	Assessment aims to update the existing RfD and derive new toxicity values for noncancer (inhalation exposure) and cancer based on available data

Next Steps: Anticipated IAP release for public comment and public science meeting in Q4 FY19

Vanadium and Compounds

Chemical Managers:

- TBD

Project history:

https://cfpub.epa.gov/ncea/iris2/chemical_landing.cfm?substance_nmbr=125

Highlights of Recent Engagement and Current Information on the IRIS Database

1987	Vanadium and Compounds to IRIS – Includes RfD (1987); no RfC, OSF, or IUR.
TBD	IRIS anticipates releasing the IRIS Assessment Plan as the next public step

Next Steps: Scoping meetings Q2-Q3 FY19



IRIS Chemical Assessment Status (Continued)

Tert-Butyl Alcohol (Tert-Butanol)

Chemical Manager:

- Janice Lee (lee.janice@epa.gov)
- Andre Weaver (weaver.james@epa.gov)

Project history:

https://cfpub.epa.gov/ncea/iris2/chemicallanding.cfm?&substance_nmbr=1036

Ethyl Tert-Butyl Ether (ETBE)

Chemical Manager:

- Andre Weaver (weaver.james@epa.gov)
- Kathleen Newhouse (newhouse.kathleen@epa.gov)

Project history:

https://cfpub.epa.gov/ncea/iris2/chemicallanding.cfm?&substance_nmbr=1034

Highlights of Recent Engagement and Current Information on the IRIS Database

2013	Preliminary Assessment Materials of the IRIS assessment of ETBE is posted and discussed at an IRIS Public Science Meeting
2016	Public Comment Draft of the IRIS assessment of ETBE is posted and discussed at an October IRIS Public Science Meeting
2017	External Peer Review Draft of the IRIS assessment of ETBE and TBA is posted and transmitted to the Science Advisory Board (SAB) Chemical Assessment Advisory Committee (CAAC)
2017	The IRIS Assessments of ETBE and TBA are discussed at a public face-to-face peer review meeting in August 2017
2019	IRIS anticipates receiving the final SAB CAAC peer review report

Next Steps: Document revision followed by Agency/Interagency review.